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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/666,581
Filing Date: September 18, 2003
Appellant(s): TOBINAGA ET AL.

MAILED

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Group 3700

Dalbert U. Shefte
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 23rd 2006 appealing from the Office action mailed November 2nd 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: as indicated in the last office action mailed November 2nd 2005, claim 33 is rejected under 35 U.S.C 103(a) as being unpatentable over Park et al (Publication Number US 2002/0082543 A1) in view of

D'Ussel (Publication No. 2004/0010237 A1); claims 12, 13 and 32 are rejected under 35 U.S.C 103(a) as being unpatentable over Park in view of D'Ussel and further in view of Arias, et al., (Pub. No. 2002/20133129 A1); claims 17 and 18 are rejected under 35 U.S.C 103(a) as being unpatentable over Park in view of D'Ussel and further in view Sherman et al., (US Patent No. 6,821,281).

(7) Claims Appendix

A substantially correct copy of appealed claims appears on page 1 of the Appendix to the appellant's brief. The minor errors are as follows: the Appendix is not labeled as a claim appendix to the appeal brief.

(8) Evidence Relied Upon

2002/0082543 A1	Park et al	12-2001
2004/0010237 A1	D'Ussel	5-2001
2002/0133129 A1	Arias et al.	3-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 14-16, 10-30 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al., (US Pub. No. 2002/0082543 A1) in view of D'Ussel (Pub. No. 2004/0010237 A1).

Park describes an applicator for applying functional substances into human skin, comprising: a base (11, see fig. 5), a plurality of microneedles (12) fixed to the base (11) and projecting therefrom a distance sufficient to penetrate into the skin, the microneedles being made of a material that is capable of disintegration and dispersion into the skin, and a functional substance carried by the microneedles for delivery by the microneedles into the skin, (paragraph 47).

Furthermore, Park et al discloses that the functional substance is distributed in the material of the microneedles, (paragraph 47).

Moreover Park describes that the functional substance is distributed homogeneously throughout the microneedles, (paragraph 46).

In addition, Park recites that the functional substance is encapsulated in the microneedles, (paragraph 45).

Furthermore, Park teaches that the base and microneedles are integrally molded from the same material, with the functional substance distributed homogenously throughout the base and microneedles, (paragraph 40).

Also, Park discloses that the microneedles are generally cone shaped, (see fig. 5).

Similarly, Park describes that the microneedles may be square, polygonal or elliptical in cross-section, (paragraph 54).

Furthermore, Park discloses that the microneedles have tips that are knife-shaped, (see fig. 5).

In addition, Park discloses that the microneedles contain microcontainers containing a functional substance, and the microcontainer is contained within the microneedle, (see fig. 3).

Moreover, Park discloses that the microneedles are formed with barbed tips and the microcontainers are disposed in the barbed tips, (see fig. 3).

Also, Park discloses that the microneedles project from said base a distance sufficient to penetrate the stratum corneum, (paragraph 119).

Furthermore, Park teaches that the microneedles project approximately 0.5 to 500μm from the base, (paragraphs 57-59).

Similarly, Park describes that the microneedles are generally cone shaped, (see fig. 5), with a diameter as base approximately 0.1 to 100μm and the microneedles that

are square, polygonal or partially elliptical in cross-section having sides or diameters approximately 0.1 to 100μm at base, (paragraphs 57-59).

In addition, Park describes that the microneedles are of sufficient projection to penetrate the dermis, (paragraph 101).

Moreover, Park discloses that the microneedles project approximately 500 to 5,000μm from the base, (paragraphs 57-59).

Similarly, Park describes, that the microneedles are generally cone shaped, (see fig. 5), with a diameter as base approximately 0.1 to 1,000μm and the microneedles that are square, polygonal or partially elliptical in cross-section having sides or diameters approximately 0.1 to 100μm at base, (paragraphs 57-59).

Park describes an applicator for applying functional substances into human skin as mentioned above, but fails to disclose that the needle material is substantially sugars, which dissolve in the human body.

D'Ussel describes a needle made substantially of sugars that dissolves within the human body, (paragraph 14).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the sugar needle of D'Ussel in order to make a more soluble delivery device of the type disclosed by D'Ussel, (D'Ussel paragraph 9).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of D'Ussel. Park et al and D'Ussel describe the device as disclosed above in

reference to claim 1 and substantially as claimed. However neither Park et al nor D'Ussel explicitly disclose that the sugar is a maltose sugar.

Applicant has not disclosed that this specific type of sugar solves any stated problem or is for any particular purpose over other sugars. Therefore it appears that the needle would perform equally well if made of a sugar as stated by D'Ussel.

Accordingly, the use of maltose is deemed to be an obvious design consideration, which fails to patentable distinguish over D'Ussel.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al., in view D'Ussel, and further in view of Arias et al (US 20020133129 A1).

Park et al., in view of D'Ussel describe an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1.

Park in view of D'Ussel fail to disclose microneedles with constricted intermediate ends.

Arias et al., describes similar microneedles with constricted intermediate ends, (see fig. 15L).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin of Park et al., in view of D'Ussel, by adding the constricted intermediate end design as taught by Arias et al., in order to make a more breakable microneedle tip.

Similarly Claims 13 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of D'Ussel and further in view of Arias et al., Park et al., in view of D'Ussel describe an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1.

Park in view of D'Ussel fail to disclose microneedles with thin outer portions and thick inner portions adjacent the base with the outer portions remaining in the skin.

Arias et al., describes similar microneedles with thin outer portions and thick inner portions adjacent the base with the outer portions remaining in the skin, (see fig. 15l).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator of Park et al., in view of D'Ussel by adding the varied thickness design of the type taught by Arias et al., in order to make a more separable microneedle tip.

Finally Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al., in view of D'Ussel and further in view of Sherman et al., (6,821,281).

Park et al., in view of D'Ussel describes an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1.

Park et al., in view of D'Ussel fails to disclose microneedles having capillary recesses in outer the portions, or capillary recesses extending along a central axis of said microneedles and are open at the outer ends of said microneedles.

Sherman et al., discloses similar microneedles with capillary recesses in outer the portions and the capillary recesses extending along a central axis of said microneedles and are open at the outer ends of said microneedles (see 38 fig. 4).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify of Park et al., in view of D'Ussel by adding the capillary recesses in outer the portions as described by Sherman et al., in order to enhance retention of the functional substances for delivery into the skin.

(10) Response to Argument

Regarding the rejection of claims 1-10, 14-16 and 19-35, applicant argues that the combination of the Park et al., and D'Ussel prior art references fails to disclose a needle made substantially of sugar.

However, D'Ussel clearly discloses in paragraphs 9 and 14 that the needle tip is made of sugar.

Next, applicant maintains that the prior art fails to disclose the elements and limitation of claims 14-16, 31, 3512 these elements and limitation are discussed above in the grounds for rejection.

The affidavit under 37 CFR 1.132 filed 02/28/2006 is insufficient to overcome the rejection of claims 1-10, and 12-25 based upon 35 USC 103(a) as set forth in the last Office action because: the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so

found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to modify the already biodegradable microneedle array device of Park et al., (paragraph 47) by making the device of a sugar as taught by D'Ussel, in order to make a more biodegradable and safer therapeutic delivery device.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Aamer S. Ahmed

Conferees:

Nicholas Lucchesi

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